

## REMARKS

In the most recently received (final) Official Action mailed September 20<sup>th</sup>, 2005, the Examiners presented applicants with the following actions:

(I) A formal withdrawl of the previous rejection of claims 11-15 under 35 U.S.C. 102(b) as anticipated by the Blecha *et al.* PCT publication [WO 96-32129];

(ii) A formal withdrawl of the previous rejection of claims 11-15 under 35 U.S.C. 102(b) as anticipated by the Chan *et al.* article [*J. Biol. Chem.* 273:28978-28985 (1998)]; and

(iii) an entirely new rejection of pending claims 11 and 13-15 under 35 U.S.C. 112, 1<sup>st</sup> paragraph as failing to comply with the written description requirement.

Applicants gratefully acknowledge and accept the Examiners' decision to withdraw each of the two earlier-made rejections based upon 35 U.S.C. 102(b). Also, in substantive response to the newly presented single basis for rejection under 35 U.S.C. 112, 1<sup>st</sup> paragraph, applicants have again amended independent claims 11 and 15 respectively; and retained the language of previously pending dependent claims 13 and 14 respectively. Accordingly, by the present amendments and the discussion presented hereinafter, applicants believe they have overcome and obviated the single

basis for rejection stated by the Examiners in the most recently received (final) Official Action dated September 20<sup>th</sup>, 2005.

### I. Applicants' Intentions And Goals

Applicants and their undersigned attorney also wish to state their intentions clearly to the Examiners of record. It is their express desire and purpose to advance the prosecution of their application on the merits, and not to delay or hinder its progress.

To achieve this goal, applicants have therefore carefully amended the two independent claims previously presented in the instant application to underscore the major defining points of the invention which are overtly described and supported in detail by the Specification text. Applicants will also directly address and substantively review the single issue and basis for rejection now presented by the Examiners in the most recently received Official Action. On this premise and for these purposes, applicants will now speak to the single basis for rejection stated by the Examiners of record in the instant Official Action, as well as present a factually accurate and legally proper basis for its resolution.

## II. The New Rejection Under 35 USC 112, 1st Paragraph

A. The Examiners' have rejected the previously pending claims as failing to comply with the written description requirement as demanded by the 1<sup>st</sup> paragraph of Section 112. However, in applicants undersigned attorney's opinion, the Examiners appear to be confused as to the precise nature and underlying cause(s) of the alleged flaws in the written description of the Specification. To demonstrate the gravity of this problem, applicants reproduce below the pertinent statements of the Examiners verbatim.

"The claims(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, has possession of the claimed invention. This is a new matter rejection." [page 2, bottom and page 3, top of the Official Action]....

"The specification indicates a member of PR-39 derived oligopeptide family is less than 39 amino acid residues, preferably less than 20 residues (page 24, lines 12-13), and further discloses the amino acid sequence of specific members such as PR-15, PR-11 and PR-8 (the N-terminal fragments of PR-39; page 25), it does not describe any particular structure to function/activity relationship in the disclosed species, the PR-39 oligopeptides which are less than 14 or 12 amino acid residues. The lack of description of the correlation of structure to function/activity, and lack of representative species for the claimed peptide, one skilled in the art would not know how to identify a functional peptide. Thus, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention" [page 3,

bottom, of the Official Action].

Taking the Examiners' own words at their face value, it appears that the Examiners are mightily struggling to identify properly and to explain clearly what are their true underlying factual reason(s) for the new rejection; and the Examiners also appear to be conceptually wrestling with several different legal doctrines in order to find some legal support for the new rejection. Thus, as is evident from the Examiners' stated language, the Examiners are repeatedly shifting their grounds for rejection and have presented applicants with a plurality of alleged flaws, all of which are specious and misleadingly attractive. Applicants note that these shifts in rationale include the following:

(1) Applicants are said to not have "possession" of the subject matter comprising the invention as a whole - despite the Examiners' overt acceptance and open acknowledgment that the Specification text as a whole provides a wide range of description and a variety of illustrative examples; and then,

(2) Applicants are said to have introduced "new matter" - despite the fact that the language of the claims did not depart from the totality of descriptive information and detailed knowledge presented by Specification text as a whole; and then,

(3) Applicants are said to have "failed to provide either a correlation of structure to function/activity relationship and failed to provide representative species for those oligopeptides which are less than 14 or 12 amino acid residues in length" - despite the Examiners' direct recognition of PR-11 and PR-8 being peptide species shorter in length than 14 or 12 residues, and the Examiners' tacit acknowledgment that the detailed recitation and informative description of peptide structure to function/activity is disclosed broadly by the illustrative examples/species at pages 24-26 of the Specification.

On this evidence, applicants therefore submit that the only demonstrable certainty in the Examiners' views and position as stated is that they are dissatisfied with the claim wording which limits the shorter length analogs of PR-39 to being peptides less than 14 or 12 amino acid residues in size. Accordingly, while the Examiners' given reasons for their dissatisfaction appear to be rather muddled, there is no question that the focus of the Examiners' instant rejection is centered upon what is and is not a proper definition of oligopeptide length in the claim language.

B. Applicants and their undersigned attorney also wish to state as a matter of formal record that the Examiners have not presented a true factual basis nor a proper legal basis for the rejection as actually stated in the instant Official Action; and that the Examiners have failed to present either

probative evidence and/or material legal support for their views and position as actually stated.

As the Examiners themselves have openly recognized and acknowledged, the Specification text describes the membership of the PR-39 derived oligopeptide family as shorter length peptides less than 39 amino acid residues in size; as preferably less than 20 residues in length; and as disclosing the specific amino acid sequences of specific members such as PR-15, PR-11, and PR-8 respectively. The Examiners also explicitly accept that these shorter-length analogs of native PR-39 peptide constitute a distinct family whose members are pharmacologically active, and provide the specified properties and characteristics which selectively inhibits proteolytic degradation mediated by proteasomes. In sum, the Examiners have not previously and do not today dispute the substance and value of all the information, details, and knowledge disclosed by the written description and the particular details of the Specification as a whole.

Applicants submit therefore that the true underlying issue presented by the instant rejection thus is not whether the inventors, at the time the application was filed, had "possession" of their invention. That specific question is well settled and is not really in dispute now. Instead, the essence and most serious part of the Examiners' argument speaks to and is concerned with whether or not the scope of protection encompassed by the

claim language is adequately supported by the written description of the Specification. It is this inquiry, and this question alone, which is the authentic issue and genuine controversy presented in earnest by the instant rejection.

In this regard, applicants and their undersigned attorney recognize there may be room for disparate assessments as to what is the overall quality and quantity of written descriptive and factual information provided by the Specification text; and, consequently, there may be marked differences in deciding what shall be the proper scope of coverage and appropriate legal protection to be encompassed by the language of the claims defining applicants' invention.

Applicants respectfully submit and affirm, therefore, that the true controversy and pertinent issue concerning the rejection in the instant Official Action is: Is the written description disclosed by the Specification text adequate to support and be commensurate with the scope of coverage encompassed by the language of the pro-offered claims?

C. Applicants also respectfully maintain that, before a determination can be made of what the proper claim language shall be, it is first necessary to understand correctly and to appreciate fully what the true legal standards and pertinent requirements actually are concerning the scope of claim

language. For this purpose, and to provide an accurate statement of adequacy of written description principles, a summary review of the appropriate legal standards is presented below.

1. One purpose of the written description requirement is to prevent an applicant from later asserting that the applicant invented that which he did not. An applicant for a patent is therefore required to recount his invention in such detail that applicant's future claims can be determined to be encompassed within applicant's original creation [Amgen Inc. vs. Hoechst Marion Roussel Inc., 65 USPQ2d 1385 at 1397 (Fed. Cir. 2003); Vas-Cath Inc. vs. Mahurkar, 19 USPQ2d 1111 at 1115 (Fed. Cir. 1991)].

2. Satisfaction of the written description requirement is measured by the understanding of a person having ordinary skill in the art. The description disclosed by the Specification text and the Drawing (if any) must clearly be adequate to allow persons of ordinary skill in the art to recognize that the inventor actually invented what is claimed [Lockwood vs. American Airlines Inc., 41 USPQ2d 1961 at 1966 (Fed. Cir. 1997)].

3. The proper test for determining whether later claimed subject matter is supported by an earlier written description is: Whether the



disclosure of the application reasonably conveys to a person skilled in the art that the inventor has possession of the additionally claimed subject matter at the time of the earlier filing [Union Oil of California vs. Atlantic Richfield Co., 54 USPQ2d 1227 at 1232 (Fed. Cir. 2000); Eiselstein vs. Frank, 34 USPQ2d 1467 at 1470 (Fed. Cir. 1995); Ralston Purina Co. vs. Far-Mar Co. Inc., 227 USPQ 177 at 170 (Fed. Cir. 1985); In re Kaslow, 217 USPQ 1089 at 1096 (Fed. Cir 1983)].

Note however, that this test is separate and distinct from the "possession of the invention" inquiry of the written description requirement; and the adequacy of description requirement is not subsumed by the "possession" inquiry [New Railhead Mfg. LLC vs. Vermeer Mfg. Co., 63 USPQ2d 1843 at 1847 (Fed. Cir. 2002)].

Thus, a showing of "possession of the invention" is ancillary to the statutory mandate that the Specification shall contain a written description of the invention; and that this requirement is not met, despite a showing of "possession", if the Specification does not adequately describe the claimed invention [Enzo Biochem. Inc. Vs. Gen-Probe Inc., 63 USPQ2d 1609 at 1617 (Fed. Cir. 2002)].

4. To satisfy the adequacy of description legal requirement, the Specification must provide information in sufficient quantity and quality that

clearly allows persons having ordinary skill in the art to recognize that the applicant invented the later claimed subject matter [Union Oil of California vs. Atlantic Richfield Co., 54 USPQ2d 1227 at 1232 (Fed. Cir. 2000); In re Gosteli, 10 USPQ2d 1614 at 1618 (Fed. Cir. 1989)]. The written description must show that applicants invented each feature that is included as a claim limitation, and the adequacy of the written description is measured from the totality of the disclosed text in the application [New Railhead Mfg. LLC vs. Vermeer Mfg. Co., 63 USPQ2d 1843 at 1847 (Fed. Cir. 2002)].

Accordingly, one skilled in the art must reasonably be able to discern the limitation at issue in the claims; and a broadly drafted claim, if presented, must be fully supported by the Specification text as a whole and the Drawing [Crown Operations Int'l. Ltd. vs. Solutia Inc., 62 USPQ2d 1917 at 1922 (Fed. Cir. 2002); Waldemar Link GmbH & Co. vs. Osteonics Corp., 31 USPQ2d 1855 at 1857 (Fed. Cir. 1994); Amgen Inc. vs. Hoechst Marion Roussel Inc., 65 USPQ2d 1385 at 1397 (Fed. Cir. 2003)].

5. Also, in order to comply with the adequacy of written description requirement, the Specification need not describe the claimed subject matter in exactly the same terms as used in the claims. Rather, the written text must simply indicate to persons ordinarily skilled in the art that, as of the filing date, the applicants had invented what is now claimed [All Dental Prodx

LLC vs. Advantage Dental Products Inc., 64 USPQ2d 1945 at 1948 (Fed. Cir. 2002); In re Wertheim, 191 USPQ 90 at 98 (CCPA 1976)].

The failure of a Specification text to mention a limitation that later appears in the claims is not fatal when one skilled in the art, after reading the Specification text, would recognize that the new claim language reflects what the Specification shows has been invented [Eiselstein vs. Frank, 34 USPQ2d 1467 at 1470 (Fed. Cir. 1995)].

Thus, while *in haec verba* identity between the word text of the Specification and the language of the claims is not required, substantive sameness between the subject matter defined by the claims and that which is described by the Specification is necessary; and what is claimed by the patent application must be substantively equal to what is disclosed by the Specification [New Railhead Mfg. LLC vs. Vermeer Mfg. Co., 63 USPQ2d 1843 at 1847 (Fed. Cir. 2002)].

D. In view of all the foregoing, applicants have therefore substantively amended the recited scope of previously pending independent claims 11 and 15 respectively. As now defined, amended independent claim 11 recites a carefully circumscribed and size-limited membership of PR-39 analog compositions which are not substantially greater than 11 amino acid residues in length. In comparison, amended independent claim 15 delineates a

restricted and size-limited membership of PR-39 analog compositions which are less than 8 amino acid residues in length.

These amended independent claims thus encompass and comprise a size-restricted family of PR-39 analog compositions which is severely limited in number; whose members are pharmacologically active; and whose membership is operative to cause a selective inhibition of protease-mediated degradation in-situ after being introduced intracellularly to a viable cell. Moreover, the commonly-shared characteristics and properties of the size-restricted family members are overtly stated and individually set forth as requisite elements and specific limitations by the language of currently amended independent claims 11 and 15 respectively.

In addition, two exemplary embodiments of this size-restricted family of oligopeptides are identified and defined by previously pending dependent claims 13 and 14 respectively. Dependent claim 13 recites a precisely stated sequence of 11 amino acid residues; and dependent claim 14 delineates a precisely recited sequence of 8 amino acid residues. Accordingly, the size-restricted family membership defined by currently amended independent claim 11 encompasses the exemplary 11 and 8 residue length embodiments; and demonstrates the intended scope and range of coverage for the claims now pending in the instant application.

Equally important, the written description as a whole disclosed by the Specification text is coextensive in scope and equal in coverage with the amended language of the presently pending claims; and the written description provides more than adequate factual support for each of the elements and limitations recited by claims 11 and 13-15 respectively. Full information and detailed knowledge of the invention defined by currently amended independent claims 11 and 13-15 is to be found at pages 23-26 of the Specification; and empirical operative support is demonstrated by Experiment 6, described at page 45 of the Specification text. Thus, that which is defined as the claimed invention is substantively equal to and properly commensurate with that which is disclosed by the written description of the Specification.

For these reasons, applicants respectfully submit that each and every claim now pending satisfies the requirements of the 1<sup>st</sup> paragraph of 35 USC 112. Accordingly, applicants respectfully request that the Examiners reconsider their stated position and withdraw this ground of rejection against the presently pending claims.

*In sum*, applicants have addressed the sole basis for rejection stated in the most recently received (final) Official Action forthrightly and objectively. In applicants' view, the single problem and issue has been

reviewed, acted upon, and resolved properly and completely. For these reasons, applicants respectfully submit and affirm that each of claims 11 and 13-15 now pending are therefore allowable.

In view of the above discussion and detailed review, applicants believe that this application is now in condition for allowance and reconsideration is respectfully requested. The Examiners are invited to call applicants' undersigned attorney should they feel that such a telephone call would further the prosecution of the present application.

Respectfully submitted,

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